

REMARKS

Claims 2-10 and 12-37 were pending in the present application. Claims 3, 5-7, 9, 10, 12-15 and 18-35 were withdrawn from consideration. Claims 2, 4, 8, 16 and 17 have been rejected by the Examiner. Claims 36 and 37 have been objected to by the Examiner. By virtue of this response, claims 2, 4, 8, 16, 17 and 26 have been amended and new claims 38-41 have been added. Accordingly, claims 2, 4, 8, 16, 17, and 36-41 are currently under consideration.

Support for the amendments and new claims is in the specification as filed at, for example, paragraphs 10, 18, 67, 68, 94, 95, 121, Example 1, Example 3, Example 8, Example 9, Figure 1, Figure 5, and Figure 6.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

In view of the preceding amendments and the remarks that follow, reconsideration and withdrawal of the outstanding objections and rejections is respectfully requested.

Interviews

Prior to addressing the issues set forth in the outstanding Office Action, Applicants' representatives (Eric Witt and Catherine Polizzi) would like to thank Examiner Walicka, Supervisor Achutamurthy, and Specialist Caputa for the courtesy extended to them during the February 5, 2004 telephonic interview, during which issues raised in the Office Action concerning indefiniteness and written description were discussed. It is noted that the Examiner did not issue an interview summary for this interview. Applicants' representative (Eric Witt) would further like to thank Examiner Walicka and Primary Examiner Prouty for the courtesy extended to him in the subsequent telephonic interview of March 19, 2004, summarized in Paper No. 20040319. These interviews were helpful in providing the response set forth herein. In particular, Applicants' representative (Eric Witt) thanks Drs. Walicka, Achutamurthy, Prouty, and Caputa for suggestions regarding amendments to claims to address written description and alleged indefiniteness. The present claims and the following Remarks reflect these suggestions.

Regarding potential prior art discussed, the Examiners identified Schasteen *et al.*, *Mol. Immunol.* (1991) 28:17-26 as a reference relating to a potential rejection under 35 U.S.C. §103. Neither the specific substance of the reference nor any specific rejection was levied or discussed. Because such a rejection has not been made of record, Applicants defer addressing this reference.

Objections

Claim 8 is objected to as depending on claim 3 belonging to the non-elected invention.

In response, claim 8 has been amended to depend from claims 2 or 4, which are in the elected invention. Applicants respectfully request that this objection be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 4, 8, 16 and 17 remain rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reasons stated on the previous Office Action, June 6, 2003 and December 3, 2002. The Office states that “recitation 1-394 of human AAT and 107 of human SLAPI [sic, “SLPI”] are indefinite as long as the sequence form [sic, “from”], which they originate, is not identified by its sequence identification No.”

Applicants maintain their arguments of record (Amendments dated April 3, 2003 and September 11, 2003). Without acquiescing to the rejection, and solely in the interest of expediting prosecution, claim 4 has been amended to identify the SEQ ID NOS. for AAT and SLPI, as suggested by the Examiner in the interview of February 5 and March 19, 2004, and reiterated in the present Office Action. Applicants respectfully request that this rejection be withdrawn.

Rejection Withdrawn

Applicants acknowledge with appreciation the withdrawal of the rejection of claims 4, 16 and 17 for the recitation of the term “about.” (Paper 20031010, page 3).

Rejections under 35 U.S.C. § 112, first paragraph

Claims 2, 4, 8 and 16-17 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking written description, for the reasons indicated in the previous office action, paper No. 12 and reiterated in the present Office Action.

Applicants maintain their arguments of record (Amendments dated April 3, 2003 and September 11, 2003).

The Office states in the present Office Action, “[T]he Applicants’ intention is a multifunctional inhibitor, see the title of the disclosure that has activities of both inhibitors, i.e., the activity of AAT and secretory leukocyte protease inhibitor.” As discussed in the interview of February 5, 2004, in order to further clarify the claim, claim 2 has been amended to recite fusion protein having alpha 1-antitrypsin protease inhibitor activity and human secretory leukocyte protease inhibitor activity, indicating the multifunctional nature of the fusion protein of the invention.

In addition, in the interview with Examiner Walicka and Primary Examiner Prouty on March 19, 2004, the Examiner suggested the deletion of the term “human” in claim 2. Claim 2 has been amended to cancel the term “human.”

The Office further states in the present Office Action that, in terms of the linkage of the protease inhibitors into fusion proteins, paragraph 69, which Applicants have pointed to in order to support written description for the linkage of the components of the claimed fusion proteins, “uses language ‘may’, therefore, interpreting claims 2, 4, and 8 in light of the disclosure is vague, because it is unknown what amino acids or pairs of them, as well as what additional sequences and their placement in the fusion protein, are included or excluded from [sic, “from”] the scope of the invention.” Applicants respectfully traverse.

The MPEP states that “Possession may be shown in many ways. For example, possession may be shown by describing *an actual reduction to practice* of the claimed invention . . .

[or] any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.” MPEP §2163.II.A.3.(a) [emphasis added]. As noted in the previous Response (September 11, 2003) and maintained herein, the fusion proteins provided by the present invention have been described both by actual reduction to practice and by a description of sufficient relevant identifying characteristics. Either alone would be sufficient to provide adequate written description, and the present specification presents both. This is true for the linkages between the components of the fusion protein. Two functional, working embodiments are provided as reduction to practice, in which the linkage is provided by a single amino acid (methionine; see, e.g., paragraph 142). Paragraph 69 describes the linkage as being any of a simple peptide bond, a single amino acid (as in the reduction to practice), or more than one amino acid. The art of production and study of fusion proteins had reached sufficient maturity at the time of application that one of skill in the art would have had no doubt from this combination of reduction to practice and description that the inventors were in possession of the claimed invention at the time of application. “Information which is well known in the art need not be described in detail in the specification.” MPEP §2163.II.A.2.

Regarding the rejection of claims 4, 8, 16, and 17 under 35 U.S.C. § 112, first paragraph (Office Action, pp. 6-8), the arguments set forth in previous responses regarding rejection of claim 2 under 35 U.S.C. § 112, first paragraph (April 3, 2003 and September 11, 2003) are equally applicable to the rejection of claims 4, 8, 16, and 17, and are extended to these claims. Without acquiescing to the rejection, and solely in the interest of expediting prosecution, claims 4, 16, and 17 have been amended to identify the SEQ ID NOS. for AAT and SLPI, as suggested by the Examiner in the interview of February 5 and March 19, 2004. Claim 8 depends from claims 2 and 4 and thus incorporates the present amendments to these claims.

In view of the above, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn

Request for rejoinder

Applicants reiterate their request for rejoinder of presently excluded method claims 26-35, to the extent that they incorporate all the limitations of the composition claims. The Office has indicated that once allowable composition claims are identified, then method claims which incorporate all the limitations of the composition claims may be rejoined (paper no. 12, page 2).

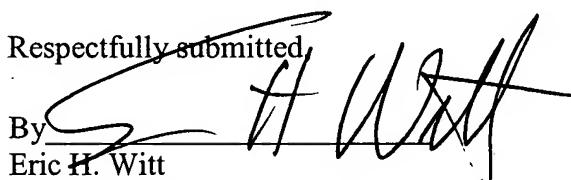
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 368292000200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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